REMARKS

Claims 38-52 and 67-93 remained withdrawn until an allowable generic or linking claim is identified.

Claim 58 has been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection of Claim 58 is respectfully traversed. A copy of the declaration filed in the case for U.S. Patent No. 5,698,244 is filed herewith. The Examiner has indicated that a declaration filed in the case for U.S. Patent No. 5,130,242 will satisfy the requirement under 35 U.S.C. 112, first paragraph. It is respectfully submitted that the enclosed declaration fulfills the Examiner's request. The accession numbers for the deposited strains have not changed.

Claims 53-56 and 59-66 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner has taken the position that the specification, while being enabling for a euryhaline microorganism of the genus *Thraustochytrium*, *Schizochytrium* and mixtures thereof, does not reasonably provide enablement for any and all euryhaline microorganisms for use in the claimed method.

The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claims. The claimed invention is enabled if one skilled in the art can make and use the invention without undue or unreasonable experimentation.

The Examiner has taken the position that the screening process disclosed in the present application is lengthy and exhaustive in its process for obtaining an appropriate euryhaline microorganism for carrying out the claimed process. However, the opposite is true. The screening process outlined in the present application is an important advance in the art. To someone experienced in screening (i.e., the skilled artisan), the collection and screening method is easy to follow without undue experimentation. Importantly, multiple strains can be screened on a single substrate simultaneously. The desired strains are easily identified on the substrate, and all that is left to do is measure the lipid content.

Prior art methods were conducted in a more linear manner, which could require undue experimentation, as suggested by the Examiner. However, the screening method taught in the present invention is designed to accomplish a number of steps simultaneously and easily (e.g., screen for size, color, heterotrophic growth, euryhalinity, thermal tolerance). Prior linear methods could require a great deal of experimentation. But the present method screens, in essentially one step, a large number of strains simultaneously for a number of desirable characteristics. Only a few screenings were needed to obtain suitable microorganisms.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) the court ruled that undue experimentation would not be required to practice an invention directed to monoclonal antibody technology. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice in the invention were well known, and that there was a high level of skill in the art at the time the application was filed. The same three criteria also apply in the present case. Therefore, that present specification meets the enablement requirement.

The Examiner has further stated that it would appear that the genera *Thraustochytrium* and *Schizochytrium* are critical to the practice of the claimed invention. This is not the case. The invention was never intended to be limited to *Thraustochytrium* and *Schizochytrium*, or even to Thraustochytriales. It is not only part of the invention, but it is also just as easy to isolate non-Thraustochytriales microorganisms as Thraustochytriales microorganisms. *Thraustochytrium* and *Schizochytrium* are merely examples of suitable microorganisms.

The Examiner has not identified or put forth any convincing rationale as to why the collection and screening method would not work to identify other suitable microorganisms. As set forth in Section 2164.04 of the MPEP, in the absence of such an explanation by the Examiner, the reasonable assertion by the Applicant that the collection and screening method enable the full scope of the invention should be accepted. Therefore, the specification enables one skilled in the art to which it pertains to carry out the process steps of the invention with other euryhaline microorganisms. It is respectfully requested that the Examiner's rejection under 35 U.S.C. 112, first paragraph be withdrawn.

The Examiner has rejected Claims 53-66 under 35 U.S.C. 101. The Examiner has taken the position that the claimed invention is directed to non-statutory subject matter. In particular, the Examiner states that the method does not clearly set forth that the euryhaline microorganisms are biologically purified and thus, that the process is not being practiced with a product of nature. The Examiner has suggested that the language --biologically purified-- be inserted before "euryhaline microorganisms" in claim 53 at step (a).

The Examiner's rejection under 35 U.S.C. 101 is respectfully traversed. It is submitted that the Examiner's point is accurate when the claim is directed to the microorganism itself. However, the present claims are directed to a process for fermentation, followed by recovery of a lipid. Such a process does not occur in nature. Therefore, it is respectfully submitted that the term --biologically pure-- does not need to be added to the pending claims.

The Examiner has objected to Claims 61-66 because abbreviations have been used. The Examiner suggested spelling out at least the first occurrence of the abbreviations in the claims. This suggestion has been complied with. Therefore it is respectfully submitted that the Examiner's objection to Claims 61-66 has been obviated.

It is respectfully submitted that all of Claims 53-66 are in condition for allowance.

It is further respectfully requested that the Examiner withdraw the restriction requirement as suggested as a possibility by the Examiner in the last Office Action. Because there are no prior art rejections outstanding, it is respectfully submitted that all of Claims 38-93 are in condition for allowance, and that the present case should be passed to issue with all Claims 38-93. In the event that the Examiner has any questions or concerns regarding the allowability of any claim, please consider this a provisional request for an Examiner's interview and please contact the undersigned attorney at 303-863-9700.

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned "Marked-Up Version Showing Amendments."

Enclosed herewith is a request for a one month extension of time and the requisite fee, to extend the time for responding from December 27, 2001, to January 27, 2002. Please debit any underpayment or credit any overpayment to Deposit Account No. 19-1970.

Respectfully submitted,

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Marked-Up Version Showing Amendments

In the Claims:

Claim 61 has been amended as shown below.

61. (Twice Amended) The process of Claim 53, wherein the ratio of docosahexaenoic acid (DHA) to eicosapentaenoic acid (EPA) in said lipids is about 7.07 or less.